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| APPLICATION NO.               | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-----------------|----------------------|---------------------|------------------|
| 09/916,176                    | 07/26/2001      | Edward R. Smith      | 036481-0134         | 7106             |
| 22428                         | 7590 07/27/2004 |                      | EXAM                | INER             |
| FOLEY AND LARDNER             |                 |                      | HAN, MARK K         |                  |
| SUITE 500<br>3000 K STREET NW |                 |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20007          |                 |                      | 3763                |                  |

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| , -1 , <sub>p</sub> u   |  | 1  |  |  |  |  |
|---|--|--|--|--|--|--|
|   | Application No.  | Applicant(s)   |  |  |  |  |
| Office Action Summers   | 09/916,176   | SMITH ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit   |  |  |  |  |
| The MAN INC DATE of the   | Mark K Han   | 3763   |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c   | correspondence address   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute,  Any reply received by the Office later than three months after the mailing  earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status  |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 11 M   |  |  |  |  |  |  |
| ,-  |  |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |  |  |  |  |  |
| closed in accordance with the practice under E  | :x рапе Quayle, 1935 С.D. 11, 49   | 53 O.G. 213.   |  |  |  |  |
| Disposition of Claims   |  |  |  |  |  |  |
| 4) Claim(s) <u>1-3 and 5-34</u> is/are pending in the application.  4a) Of the above claim(s) <u>5,6,8-16,26,27 and 31-33</u> is/are withdrawn from consideration.  |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-3, 7, 17-25, 28-30 and 34</u> is/are reje   | ected.   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |  |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o  | r election requirement.  |  |  |  |  |  |
| Application Papers  |  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |  |  |  |  |  |  |
|   | 10) ☐ The drawing(s) filed on 26 July 2001 and 11 May 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Ex  |  |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  | •  |  |  |  |  |  |
|   | ndosity under 25 H C C 5 440/o   | \  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  |  |  |  |  |  |  |
| 2. Certified copies of the priority document  | s have been received in Applicat   | ion No   |  |  |  |  |
| 3. Copies of the certified copies of the prior  | · •  | ed in this National Stage  |  |  |  |  |
| application from the International Bureau   |  | a d  |  |  |  |  |
| * See the attached detailed Office action for a list  | or the certified copies not receive  | su.  |  |  |  |  |
| Attachment(s)   |  | •  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)   | 4) 🔲 Interview Summary   |  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  | Paper No(s)/Mail D  5) Notice of Informal F  | ate Patent Application (PTO-152)   |  |  |  |  |
| Paper No(s)/Mail Date   | 6) Other:  |  |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Applicant's election without traverse of the species depicted in Figure 3 in the reply filed on 22 September 2003 is acknowledged.
- 2. Claims 5, 6, 8-14, 16, 26, 27 and 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 22 September 2003. Additionally, it is believed that claim 15 is drawn to a nonelected species depicted in Figure 7. Therefore, claim 15 has also been withdrawn from further consideration.
- 3. In response to Applicants' remarks regarding Examiner's withdrawal of claims (p. 8, paragraphs 1-2, filed 11 May 2004, Examiner asserts that claim 15 had been correctly withdrawn. On p. 2 of the Office Action mailed 19 November 2003, it is clearly noted that claim 15 would be withdrawn from consideration as being drawn to a nonelected species. Applicants' remarks incorrectly asserted that claim 15 was indicated as pending. There was never a discrepancy regarding the status of claim 15 in the Office Action mailed 19 November 2003. Claim 15 will not be considered on its merits and will be withdrawn from consideration for the reasons described above.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 7, 17-25, 28-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,630,796 to Bellhouse et al. (hereinafter "Bellhouse").

Bellhouse discloses a needleless injector having a cassette 28 that has a first cassette part 30, first rupturable membrane 33, second cassette part 31, second rupturable membrane 34 and particles 32. See Figures 1 and 8. Bellhouse also describes the claimed method in col. 12, lines 29-43 in the specification. With regards to the limitation that the first and second cassette parts being attachable together by an interference fit, Bellhouse does not explicitly disclose such a fit but merely indicates that first cassette part 30 is disposed about second cassette part 31. It is considered well-within the ordinary level of skill of the artisan to readily form an interference fit between two parts intended to be in sealing engagement with each other. It would have been obvious to one of ordinary skill in the art to use an interference fit between the cassette parts of Bellhouse in order prevent two parts from easily separated.

## Response to Arguments

5. Applicant's arguments with respect to claims 1-3, 7, 17-25, 28-30 and 34 have been considered but are moot in view of the new ground(s) of rejection.

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## Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K Han whose telephone number is 703-308-4543. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mlh.

Mark Han
Patent Examiner
Art Unit 3763

mkh July 22, 2004

> MICHAEL J. HAYES PRIMARY EXAMINER

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